PATENT Attv. Dkt. No. ACAD/0002 Serial No.: 10/612,594

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE §

In re Application of:

HWANG et al.

Serial No.: 10/612.594

Filed:

July 1, 2003

For: EXPRESSION OF ZEBRAFISH BONE MORPHOGENETIC PROTEIN 4

Mail Stop: AMENDMENT Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

000000000 Group Art Unit: 1646

Conf. Number: 3435

Examiner: Elizabeth C. Kemmerer, Ph.D.

CERTIFICATE OF FLECTRONIC FILING

I hereby certify that this correspondence and the documents referred to as attached therein are being electronically filed on

June 16, 2006. 106

## **RESPONSE TO RESTRICTION REQUIREMENT DATED MAY 16, 2006**

In response to the Restriction Requirement dated May 16, 2006 having a shortened statutory period for response set to expire on June 16, 2006, please enter this response and reconsider the claims pending in the application for reasons discussed below. Although Applicant believes that no additional fees are due in connection with this response, the Commissioner is hereby authorized to charge counsel's Deposit Account No. 20-0782/ACAD/0002/JYC, for any fees, including extension of time fees or excess claim fees, required to make this response timely and acceptable to the Office.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper. Remarks begin on page 4 of this paper.

## IN THE CLAIMS:

Please cancel claims 6-19 without prejudice and replace the claims as follows:

- (Original) An isolated DNA molecule encoding a zebrafish bone morphogenetic protein 4 gene, comprising a nucleic acid sequence selected from the group consisting of SEQ. ID NO. 1, SEQ. ID NO. 4, SEQ. ID NO. 7, SEQ ID NO. 8, SEQ ID NO. 9 and derivatives and fragments thereof.
- 2. (Original) A recombinant expression vector comprising a portion of the isolated DNA molecule of claim 1.
- (Original) The recombinant expression vector of claim 2, wherein the portion
  of the isolated DNA molecule is operatively linked to a nucleotide sequence encoding a
  heterologous expression product.
- 4. (Original) The recombinant expression vector of claim 3, wherein the heterologous expression product is a reporter protein selected from the group consisting of  $\beta$ -galactosidase, luciferase, chloramphenicol acetyl transferase (CAT), green fluorescent protein (GFP), human growth hormone, alkaline phosphatase,  $\beta$ -glucuronidase, and combinations thereof.
- 5. (Original) A cell comprising the isolated DNA molecule of claim 1.
- 6-19. (Cancelled).
- (Original) An isolated tissue-specific transcriptional regulatory DNA fragment comprising a DNA sequence selected from the group consisting of SEQ. ID NO. 1, SEQ. ID NO. 7, SEQ. ID NO. 8, SEQ. ID NO. 9, and derivatives and fragments thereof.
- 21. (Original) The isolated tissue-specific transcriptional regulatory DNA fragment of claim 20, wherein the DNA sequence is derived from SEQ. ID NO. 1, and derivatives and fragments thereof for directing heart-specific expression.

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22. (Original) The isolated tissue-specific transcriptional regulatory DNA fragment of claim 20, wherein the DNA sequence is derived from SEQ. ID NO. 1, SEQ. ID NO. 7, SEQ. ID NO. 8, SEQ. ID NO. 9, and derivatives and fragments thereof for directing expression in tissues and organs selected from the group consisting of eyes, otic vesicles, hatching gland, anus, caudal fin and combinations thereof.

23.-45. (Cancelled)

## REMARKS

This is intended as a full and complete response to the Restriction Requirement dated May 16, 2006, having a shortened statutory period for response set to expire on June 16, 2006. Please reconsider the claims pending in the application for reasons discussed below.

Claims 1-22 remain pending in the application and are shown above. Claims 6-19 stand withdrawn by the Examiner and claims 6-19 are cancelled without prejudice. Claims 1-5, 20-22 are subject to restriction and election requirement. Applicant elects Group I, claims 1-5 and 20-22 with traverse. Applicant reserves the right to pursue the subject matter of the cancelled claims at a later date. Reconsideration of the Restriction Requirement is requested for reasons presented below.

The Examiner states that restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. Claim 1-5 (each in part), 20 (in part), 21, and 22 (in part), drawn to a nucleic acids of SEQ ID NO: 1 and generically claimed derivatives and fragments thereof, classified in class 536, subclass 23.1, for example.
- II. Claim 1-5 (each in part), drawn to a nucleic acids of SEQ ID NO: 4 and generically claimed derivatives and fragments thereof, classified in class 536, subclass 23.1, for example.
- III. Claim 1-5, 20 and 22 (each in part), drawn to a nucleic acids of SEQ ID NO: 7 and generically claimed derivatives and fragments thereof, classified in class 536, subclass 23.1, for example.
- IV. Claim 1-5, 20 and 22 (each in part), drawn to a nucleic acids of SEQ ID NO: 8 and generically claimed derivatives and fragments thereof, classified in class 536, subclass 23.1, for example.
- V. Claim 1-5, 20 and 22 (each in part), drawn to a nucleic acids of SEQ ID NO: 9 and generically claimed derivatives and fragments thereof, classified in class 536, subclass 23.1. for example.

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The Examiner states that the inventions are distinct, each from the other because invention I-V are not disclosed as capable of use together and have different effects, and SEQ ID NOS: 1, 4, 7, 8, and 9 are non-overlapping nucleic acid sequences that have different regulatory functions, each requiring its own search and undue search burden.

Applicant elects with traverse a single disclosed species of SEQ NO. 1 of a zebrafish bone morphogenetic protein 4 gene, as recited in claims 1-5 and 20-22. Applicant respectively traverses the restriction requirement on grounds that a reasonable number of species are claimed. According to MPEP § 803.04, "...... subject to a restriction requirement pursuant to 35 U.S.C. §121 and 37 CFR §1.141 et seq. Nevertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Director has decided sua sponte to partially waive the requirements of 37 CFR §1.141 et seq. and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See Examination of Patent Applications Containing Nucleotide Sequences, 1192 O.G. 68 (November 19, 1996). It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined. Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together. "

Accordingly, only 5 nucleotide sequence species are claimed and all of them are form the same zebrafish bone morphogenetic protein 4 gene. Applicant respectfully request withdrawal of this species restriction requirement and prosecution of claims 1-5 and 20-22.

Having addressed all issues set out in the Restriction Requirement, Applicant respectfully submits that the claims are in condition for allowance and respectfully request that the claims be allowed.

Respectfully submitted,

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